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Review Study *Medical research*

Safety and efficacy of remdesivir on treatment of covid -19: A systematic review

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ABSTRACT

Background: The coronavirus disease 2019 (COVID- 19) has become a world health crisis. Remdesivir as first officially approved agent for Covid-19 treatment, we performed a systematic review to judge the protection and efficacy of remdesivir in Covid-19 patients.

Method: During this systemic review, search data obtained from various electronic databases like PubMed, medRxiv.org, google scholar and in www.Clinical Trials. gov for ongoing RCTs. A probe strategy was developed for every database without restrictions for language or years considered. We identified 52 articles, among which 24 full text article are chosen, we rejected article which aren't relevant to the study.

Results: The foremost important final health outcome and also all the four studies assessed the protection of this drug by measuring overall serious adverse events. No differences in all-cause mortality, SAEs or AEs were seen among the 5-day, 10-day and standard of care arms within the Spinner et al., trial. We agree that the currently available data isn't sufficiently strong to support its FDA approval, provided that it's impractical to completely assess the balance of advantages to harm in COVID-19 infected patients.

Conclusion: The findings provide corroborating evidence of clinical improvement in randomized, placebo controlled trials of remdesivir therapy. Our findings suggest that remdesivir merits extended clinical use and and should even be efficacious among non severe hospitalized COVID-19 patients.

Keyword: "Covid-19" "Remdesivir" "safety and efficacy"

INTRODUCTION

Corona viruses belongs to an oversized virus family, usually targeting the respiratory system. The name is being derived from the Latin word corona, meaning crown, because of the spiky fringe which surrounds these viruses. Many species such as bats, cats and birds get sick due to this viral infection. Just seven are known to infect humans like Covid-19, SARS and MERS.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was identified in December 2019 in Wuhan city, China. As of May 8th, 2020, the World Health Organization (WHO) had documented 3,759,967 positive Covid-19 cases, and therefore the death attributed to COVID-19 had reached 259,474 worldwide. [1] The primary SARS-CoV-2 positive case in India was reported with the state of Kerala on January 30th, 2020. A complete of 14,37,788 suspected samples had been sent to the National Institute of Virology (NIV), Pune, and a related testing laboratory according to the press released by the Indian Counsil of Medical Research on 8th May, 2020. [2]

The recent outbreak of COVID-19 in several countries is analogous to the previous outbreaks of SARS and MERS that emerged in 2013 and 2912 in China and Soudi Arabia, respectively. [3-5] There's no particular treatment available to treat SARS, there's some evidence that time to SARS-CoV-2 being kind of human coronavirus HKU1 and 229E strains. [6-7]

AIM

The aim of this review study is to assess the safety and efficacy of Remdesivir in the treatment of Covid-19.

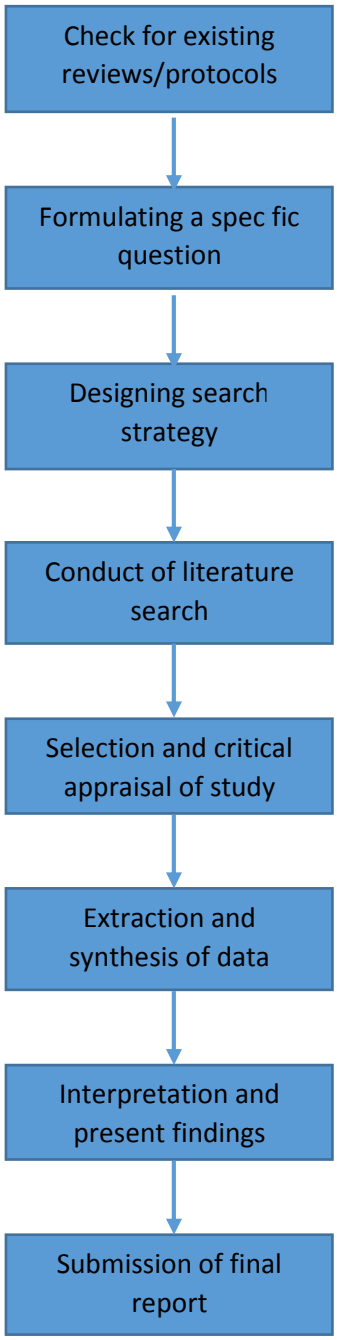
OBJECTIVE

- To analyse the effectiveness of the treatment using remdesivir in COVID 19 cases.
- To evaluate overall serious adverse event after initiation of treatment.
- To assess all cause mortality at day 14 of treatment

METHDOLOGY

The study evaluating the remdesivir in adults were searched in several search engines. Primary outcomes included are improvement,recovery and high adverse event. Meta-analysis were performed.

PLAN OF WORK



RESULTS

Author	Study	Year of Publishing	Outcome
Piscoya *et al*	Efficacy and harms of remdesivir for the treatment of COVID-19	2020	There's paucity of adequately powered and fully reported RCTs evaluating effects of remdesivir in hospitalized

			COVID-19 patients
Azza Sarfraz *et al*	Randomized controlled trials of remdesivir in hospitalized COVID-19 patients	2020	Remdesivir extends clinical benefits by reducing mortality,adverse events and oxygen support in moderate to severe ill COVID-19 patients

Author	Study	Year of publishing	Outcome
Arif Musa *et al*	Remdesivir for the Treatment of COVID-19	2020	There's both in vitro and limited clinical evidence that supports the employment of remdesivir to treat SARS-CoV-2. However, Phase 3 clinical trials haven't yet been completed and partial data has not yet been reported. The side-effects profile of remdesivir remains similarly not well defined.

Author	Study	Year of Publishing	Outcome
Min Seo Kim *et al*	Comparative efficacy and safety of pharmacological interventions for the treatment of COVID-19	2020	There's both in vitro and limited clinical evidence that supports the employment of remdesivir to treat SARS-CoV-2. However, Phase 3 clinical trials have not yet been completed and partial data has not yet been reported. The side-effects profile of remdesivir remains similarly not well defined.Anti-inflammatory agents (tocilizumab, anakinra, and IVIG) and remdesivir may safely and effectively improve outcomes of hospitalized COVID-19 patients. Only 20% of current evidence on pharmacological management of COVID-19 is on moderate and high evidence certainty and may be considered in practice and policy; remaining 80% are of low or very low certainty and warrant further studies to ascertain firm conclusions.

DISCUSSION

The present study was performed to systematically review the efficacy of remdesivir compared to placebo among adult hospitalized, RT-PCR confirmed patients with Coronavirus infection 2019. The inclusion criteria were specific for adult hospitalized COVID19 patients treated either remdesivir or placebo.

The overall mortality is that the most significant final health outcome and also all the four studies assessed the protection of this drug by measuring overall serious adverse events. Wang et al., RCT was stopped prematurely due to an excess of serious adverse events causing drug discontinuation. The demographic differences, with more remdesivir patients having hypertension, diabetes or CAD would be more likely to figure against remdesivir efficacy. No differences in all-cause mortality, SAEs or AEs were seen among the 5-day, 10-day and standard of care arms within the Spinner et al., trial.

Remdesivir is FDA approved and indicated for the treatment of hospitalized COVID-19 patients who are 12 years old and older and who weigh a minimum of 40 kg. It should be administered during a hospital or in a very healthcare setting capable of providing acute care comparable to inpatient hospital care. We agree that the currently available data isn't sufficiently strong to support its FDA approval, provided that it is not possible to totally assess the balance of benefits to harm in COVID-19 infected patients. There is a drawback that the safety and efficacy of remdesivir will remain unclear if other remdesivir RCTs vs. placebo are stopped and substituted with trials where remdesivir becomes the standard of care and other experimental drugs are added onto remdesivir versus remdesivir alone.

This systematic review has several strengths because an extensive systematic search engines and websites were used and not restricted by language and Congruities across all studies was found: adult, hospitalized patients with COVID-19 and in specifically patients with pneumonia and respiratory insufficiency. All four studies evaluated the identical loading dose and a identical daily dose and two RCTs were compared to placebo, two RCTs compared two different doses of remdesivir, including one RCT with standard of care.

CONCLUSION

The findings provide evidence of clinical improvement in randomized, placebo controlled trials of remdesivir therapy. One RCT was stopped early without a description of explanation, the biggest trial (Beigel et al. ACTT-1), altered their primary endpoint twice and only reported 15-day outcomes. Conclusion about overall mortality and SAEs from meta-analyses of two trials should be interpreted with caution. Additionally, the efficacy of 5 days versus 10 days dosing of remdesivir needs requires further exploration. Several ongoing RCTs should be completed despite the FDA approval in order to work out remdesivir's clinical efficacy and safety profile. Our findings suggest that remdesivir merits extended clinical use and should even be efficacious among non severe hospitalized COVID-19 patients.

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